Iliac artery stenting in patients with poor distal runoff: Influence of concomitant infrainguinal arterial reconstruction

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Objective: **Inadequate infrainguinal runoff is considered an important risk factor for iliac stent failure. However, the influence of concomitant infrainguinal arterial reconstruction (CIAR) on iliac stent patency is unknown. This study evaluated the influence of CIAR on outcome of iliac angioplasty and stenting (IAS) in patients with poor distal runoff.**

Methods: **Over 5 years (1996 to 2001), 68 IAS procedures (78 stents) were performed in 62 patients with poor distal runoff (angiographic runoff score ≥5). The SVS/AAVS reporting standards were followed to define outcome variables and risk factors. Data were analyzed with both univariate analysis (Kaplan-Meier method [K-M]) and regression analysis (Cox proportional hazards model).**

Results: **Indications for iliac artery stenting were disabling claudication (59%) and limb salvage (41%). Of the 68 procedures, IAS with CIAR was performed in 31 patients (46%), and IAS alone was performed in 37 patients (54%). Patients undergoing IAS with CIAR were older (P = .03) and had more extensive and multifocal iliac artery occlusive disease, with more TASC (TransAtlantic Inter-Society Consensus) type C lesions (P = .03), compared with patients undergoing IAS alone. No other significant differences in risk factors were noted. Runoff scores between patients undergoing IAS with CIAR and those undergoing IAS alone were not significantly different (median runoff scores, 6 [range, 5-8] and 7 [range, 5-9], respectively; P = .77). Primary stent patency rate at 1, 3, and 5 years was 87%, 54%, and 42%, respectively, for patients undergoing IAS with CIAR, and was 76%, 66%, and 55%, respectively, for patients undergoing IAS. Univariate analysis revealed that primary stent patency rate was not significantly different between the 2 groups (K-M, log-rank test, P = .81). Primary graft patency rate for CIAR was 81%, 52%, and 46% at 1, 3, and 5 years, respectively. Performing CIAR did not affect primary iliac stent patency (relative risk, 1.1; 95% confidence interval, 0.49-2.47; P = .81). Overall, there was a trend toward improved limb salvage in patients undergoing IAS with CIAR, compared with those undergoing IAS alone (K-M, log rank test, P = .07).**

Conclusion: **In patients undergoing IAS with poor distal runoff, CIAR does not improve iliac artery stent patency. Infrainguinal bypass procedures should therefore be reserved for patients who do not demonstrate clinical improvement and possibly for those with limb-threatening ischemia. (J Vasc Surg 2003;38:479-85.)**

Iliac angioplasty and stenting (IAS) is an established option for treatment of iliac artery occlusive disease.[1-4] However, risk factors for primary iliac artery stent failure have been identified, and include female sex, poor runoff, and presence of external iliac artery lesions.[1,3-5] In theory, poor runoff could be improved with concomitant infrainguinal arterial reconstruction (CIAR) that bypasses the infrainguinal lesions that account for the adverse outflow, but this has not been proved. Although IAS with CIAR has been used more recently for arterial reconstructions in patients with multisegmental arterial occlusive disease, the outcome of these combined procedures is not well known.[6-11] Furthermore, performing CIAR is not always justified in patients with iliac and infrainguinal arterial occlusive disease, because in most of these patients only intervention to treat aortoiliac lesions is required.[12]

This study was designed to assess the need and efficacy of CIAR in patients undergoing IAS to treat iliac artery occlusive disease associated with poor infrainguinal runoff. The most current recommendations and standards were used to define the different variables.[13-15]

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METHODS

Among 394 IAS procedures performed from July 1996 to December 2001, 68 (78 stents) were performed in 62 patients with iliac artery lesions associated with poor distal runoff. Runoff was determined from preoperative and intraoperative arteriograms, according to the criteria prepared and revised by the Ad Hoc Committee on Reporting

Standards of the Society for Vascular Surgery and the American Association for Vascular Surgery (SVS/AAVS).[13,15] Only patients with iliac artery lesions in whom runoff score at angiography was 5 or higher were included in the study. Infrainguinal bypass grafting performed within 30 days of iliac stent placement was considered a concomitant procedure intended to improve distal runoff. Patients undergoing infrainguinal arterial reconstruction after 30 days or before IAS were not included. Likewise, patients undergoing IAS combined with infrainguinal endovascular procedures and those undergoing iliac angioplasty alone with CIAR were excluded. All patients had evidence of chronic limb ischemia and were included in a retrospective cohort study. Preoperative, intraoperative, and follow-up information was available for all patients, and was obtained via office and hospital chart review, dictated operative records, and telephone conversations with patients, family members, or physicians. The study protocol was approved by the local institutional review board.

Endovascular procedures were performed in the operating room by vascular surgeons. Arteriography was performed through an ipsilateral or contralateral femoral approach. Primary or selective stent placement was performed at the discretion of the physician performing the procedure. Patients underwent primary stenting when stents were deployed as the primary method of treatment of iliac lesions rather than for treatment of suboptimal results after iliac angioplasty alone (selective stenting). Balloon-expandable stents (Palmaz or Palmaz Genesis stents, Cordis J and J, Warren, NJ; and AVE Bridge stents, Medtronic/AVE, Santa Rosa, Calif) were used preferentially to treat focal lesions, severely calcified lesions, and all lesions adjacent to the aortic bifurcation. Self-expandable stents (Wallstent, Boston Scientific Vascular, Natick, Mass; Cordis SMART Stents, Cordis J and J; or Bridge SE stents, Medtronic/AVE) were usually placed in patients with long-segment disease or tortuous iliac arteries and for contralateral approaches. Pressure gradient was determined, primarily to evaluate moderate (30%-50%) stenosis and residual moderate and severe (>30%) stenosis, and to document hemodynamic improvement of these lesions. Stent placement was deemed technically successful if there was less than 30% residual stenosis and the gradient across the treated lesion was less than 5 mm Hg. The decision to perform CIAR was at the discretion of each responsible surgeon.

Iliac artery stent and infrainguinal artery bypass graft patency rates were determined with the SVS/AAVS criteria.[15] Primary patency was defined as a patent stent or graft without recurrent stenosis or need for further intervention. There was no strict postoperative surveillance protocol. However, patients were usually seen within 2 weeks after the procedure. Improvement and changes in clinical status were determined with history and noninvasive vascular laboratory tests. Postoperative follow-up (clinical and serial duplex ultrasound scanning examinations) was conducted every 3 months during the first postoperative year and every 6 months thereafter. Arteriography was performed when noninvasive arterial testing revealed a decrease in ankle-brachial index of 0.15 or more or if duplex scanning peak systolic velocity ratio across the treated lesion was greater than 2.5. Indications for repeat intervention included stenosis greater than 60% and gradient across the lesion greater than 15 mm Hg with papaverine or greater than 10 mm Hg at rest. All revisions performed based on these criteria or occlusion were considered stent failure and the end of primary patency.[15] Survival could be established by telephone contact, but patency and limb salvage were determined at the most recent examination.

All analyses were performed according to intention to treat, that is, including initial technical failures. Continuous variables were expressed as median and range, and were analyzed with the Mann-Whitney U test for unpaired comparisons. Exact P values are given, and $P < .05$ is considered significant. Univariate analysis of categorical variables was performed with the χ^2 test (χ^2 for independent groups, two-tailed P value) or Fisher exact test, as appropriate. Primary patency, limb salvage, and patient survival were determined with the Kaplan-Meier method (K-M), and differences with the log-rank test.[16] Cox proportional hazards model with time-dependent covariate was used for regression analysis, to assess the influence of various risk factors on primary patency, limb salvage, and patient survival.[17] Variables with P value less than .25 at univariate analysis and those known to be important or possible confounding factors were entered into the regression model and considered significant by forward stepwise selection if P was less than .05 in the final regression equation. The relative risk (RR) and 95% confidence interval (95% CI) for the different variables were estimated with this method.[17] For statistical analyses, SPSS for Windows (version 10.0; SPSS Inc, Chicago, Ill) was used.

RESULTS

Patients and procedures. Patient median age was 64 years (range, 42-83 years). The most commonly associated risk factors were history of smoking (80%), hypertension (79%), coronary artery disease (74%), hyperlipidemia (64%), and diabetes mellitus (43%). Indications for revascularization were disabling claudication in 40 procedures (59%) and limb salvage in 28 procedures (41%; ischemic rest pain in 8 [12%], tissue loss in 20 [29%]). Median preoperative ankle-brachial index at rest was 0.54 (range, 0-0.88). Median follow-up was 34 months (range, 3-60 months).

Iliac stents were placed primarily in 24 procedures (36%), and selective stenting was performed because of significant residual stenosis or pressure gradient after angioplasty (55%) and dissection after balloon angio-

Table I. Clinical characteristics of patient groups: IAS with CIAR group and IAS alone group

	IAS with CIAR group (%) (n = 27)	*IAS alone group (%) (n = 35)*	P *value*
Median age	69	57	.03*
Female sex	9 (33)	13 (38)	.96
Limb-threatening ischemia	15 (56)	11 (31)	.09†
Comorbidities			
Diabetes mellitus	10 (36)	17 (48)	.52
Hypertension	23 (81)	26 (74)	.46
Tobacco abuse	22 (71)	32 (83)	.28
Coronary artery disease	23 (81)	28 (80)	.74
Hyperlipidemia	19 (71)	22 (63)	.26

IAS, Iliac angioplasty and stenting; CIAR, concomitant infrainguinal arterial reconstruction.
* Mann-Whitney *U* test.
† χ^2 analysis.

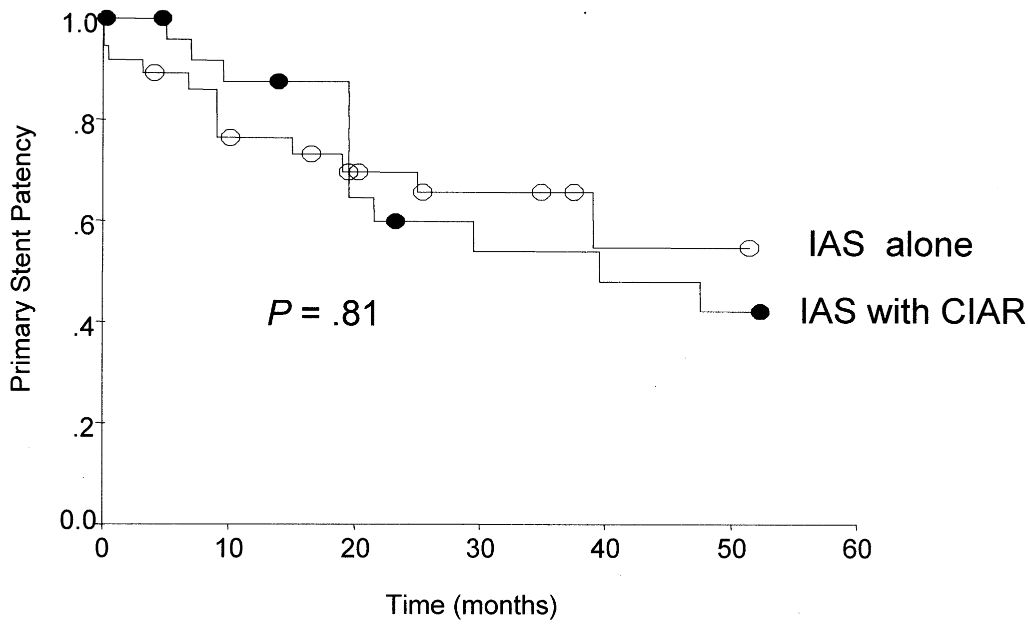
Table II. Distribution, characteristics and procedural factors of 68 iliac angioplasty and stenting procedures comparing IAS with CIAR group and IAS alone group

	IAS with CIAR group (%) (n = 31)	*IAS alone group (%) (n = 37)*	P *value*
Angiographic runoff score (median)	6 (5-8)	7 (5-9)	.77*
Iliac occlusion	2 (6)	3 (8)	1.00
TASC stratification of iliac lesions			
Type A	2 (6)	5 (14)	.44
Type B	9 (29)	20 (54)	.06†
Type C	19 (61)	11 (30)	.03†
Type D	1 (3)	1 (3)	1.00
Primary stent placement	9 (29)	12 (32)	.97
Stent type			
Balloon-expandable	11 (35)	21 (57)	.13
Self-expanding	19 (61)	15 (41)	.14
Both	1 (3)	1 (3)	1.00
Superficial femoral artery			
Stenosis	14 (45)	13 (35)	.55
Occlusion	17 (55)	24 (65)	.55
Tibial artery patency			
3 vessel	7 (23)	6 (16)	.72
2 vessel	17 (55)	19 (51)	.96
1 vessel	7 (23)	12 (32)	.53

IAS, Iliac angioplasty and stenting; CIAR, concomitant infrainguinal arterial reconstruction; *TASC,* Trans Atlantic Inter-Society Consensus.
* Mann-Whitney *U* test.
† χ^2 analysis.

plasty (9%). Balloon-expandable stents were used in 32 procedures (46%), self-expanding stents in 34 procedures (50%), and a combination of both stents in 2 procedures (4%). Stents were placed in 5 (7%) TransAtlantic Inter-Society Consensus (TASC) type A iliac lesions, 27 (40%) type B lesions, 30 (44%) type C lesions, and 6 (9%) type D lesions. Twenty-nine (43%) stent placement procedures were performed to treat common iliac artery lesions, 10 (15%) to treat external iliac artery lesions, and 29 (43%) to treat lesions in both arteries. Initial technical success was obtained in 66 procedures (97%). CIAR was performed in 31 patients (46%). Twenty-five CIARs (37%) were performed at the same operative setting as IAS. Autogenous vein was used in 20 CIARs (65%), polytetrafluoroethylene graft in 9 (29%), and polytetrafluoroethylene-vein composite grafts in 2 (6%). Nine CIARs were femoral to above-knee popliteal (29%), 15 were femoral to below-knee popliteal (48%), and 7 were femorotibial (23%). The common femoral artery was the inflow artery in all patients.

Univariate analyses revealed that patients undergoing IAS with CIAR were older than those undergoing IAS alone (median age, 69 and 57 years, respectively; $P = .03$), but no other significant differences in comorbidity were noted (Table I). Iliac artery occlusive disease was more extensive and multifocal in the group with IAS with CIAR, with more TASC type C lesions than in the group with IAS alone (61% vs 30%; χ^2 test, $P = .03$; Table II). Of impor-



IAS alone group							
At risk	31	23	15	12	10	4	2
S.E.	.000	.067	.078	.092	.101	.101	.101
IAS with CIAR group							
At risk	37	25	18	15	13	8	2
S.E.	.000	.041	.066	.086	.099	.101	.101

Primary iliac artery stent patency rate was not significant between patients undergoing iliac angioplasty and stenting (IAS) with concomitant infrainguinal arterial reconstruction (CIAR) compared with those undergoing IAS alone (Kaplan-Meier method, log-rank test, P = .81).

tance, runoff scores were not significantly different between the two groups; median runoff score for patients undergoing iliac artery angioplasty and stenting with concomitant infrainguinal arterial reconstruction was 6 (range, 5-8), and for patients undergoing iliac artery angioplasty and stenting alone was 7 (range, 5-9).

Initial results. Initial technical success was obtained in 66 iliac endovascular procedures (97%). Hemodynamic success and clinical improvement, as defined by the SVS/AAVS reporting standards, was obtained in 95% of patients.[15] Forty-six percent of patients demonstrated clinical improvement to category +3, 39% to category +2, and 10% to category +1. In 1% of patients clinical status was unchanged, and was worse in 3%: category 1, 1%; category 2, 1%; category 3, 1%. Local complications included superficial wound infection in 5 patients (7%) and deep infection that required drainage in 1 patient (1%). No graft or stent infection occurred. One operative (30-day) death occurred after myocardial infarction in a patient who underwent IAS with CIAR.

Long-term results. Cumulative primary stent patency rate for all IAS procedures at 1, 3, and 5 years was 84%, 59%, and 48%, respectively. Patients undergoing IAS with CIAR did not have significantly different primary stent patency compared with those undergoing IAS alone, at univariate analysis (K-M, log-rank test, P = .81) (Figure). Primary stent patency rates at 1, 3, and 5 years were 87%, 54%, and 42%, respectively, in patients undergoing IAS with CIAR, and 76%, 66%, and 55%, respectively, in patients undergoing IAS alone. When initial technical failures were excluded, 5-year primary patency rate was 42% after IAS with CIAR and 58% after IAS alone, which was not statistically different at survival analysis (K-M, log-rank test, P = .52). Univariate analysis revealed a trend in women and smokers toward decreased primary stent patency (K-M, log-rank test, P = .06), whereas primary stent patency rate was not significantly different with respect to other risk factors. Regression analysis did not reveal any independent predictors for decreased primary stent patency. CIAR did not affect primary iliac stent patency (RR, 1.1; 95% CI, 0.49-2.47; P = .81). Stratified analysis adjusted for grade of ischemia was limited by insufficient number of patients in the various subgroups. In patients with critical ischemia, however, there was a trend for higher iliac stent patency after IAS with CIAR compared with IAS alone (3-year primary stent patency rate, 83% and 56%, respectively; K-M, log rank test, P = .16). This trend was not observed in patients with disabling claudication.

Cumulative primary graft patency rate for all CIAR was 81%, 52%, and 46% at 1, 3, and 5 years, respectively. Univariate and regression analysis did not identify independent predictors for primary graft failure after CIAR.

For all patients, limb salvage rate at 1, 3, and 5 years was 99%, 91%, and 88%, respectively. Univariate survival analysis revealed a trend for improved limb salvage in patients undergoing IAS with CIAR, compared with patients undergoing IAS alone (K-M, log rank test, $P = .07$). Overall, long-term survival was 92% at 1 year, 87% at 3 years, and 78% at 5 years.

DISCUSSION

The results of our study indicate that CIAR does not improve iliac stent patency in patients undergoing IAS to treat iliac lesions associated with significant infrainguinal arterial disease. Inasmuch as several observational studies,[1,2] including our own experience,[5] have established that poor runoff is an independent predictor for adverse outcome after IAS, our findings provide a helpful guide in determining need for and efficacy of CIAR in patients undergoing IAS who also have significant infrainguinal disease. To determine which patients would benefit from IAS with CIAR, stratified analyses according to grade of ischemia were included in this study. Although the severity of ischemia was not significantly different between patients undergoing IAS with CIAR and IAS alone, CIAR was performed more frequently in patients with limb-threatening ischemia, which suggests that critical ischemia was an important factor in the decision to perform CIAR. Nonetheless, 38% of patients with disabling claudication also underwent IAS with CIAR. Stratified analysis to investigate the influence of CIAR on outcome of IAS in patients with limb-threatening ischemia was limited in this series, because of the small sample size in this subgroup of patients. However, there was a trend for higher iliac stent patency and improved limb salvage after IAS with CIAR, compared with IAS alone. This trend was not seen in patients with claudication. Thus infrainguinal arterial reconstruction may be necessary only if there is no clinical improvement in patients with disabling claudication after IAS, and probably in those with critical ischemia.

A possible type II statistical error was considered in the data analysis, because of the small sample size. A post hoc power analysis was obtained to assess the beta error, and was based on our previous publication.[5] In the previous study, poor runoff was associated with a threefold increased risk for primary iliac stent failure (RR, 3.1; 95% CI, 1.8-5.5). CIAR would be effective only if such risk could be reduced. Sample size calculation revealed that the data set was large enough to obtain 80% power, with a two-sided *P* value of .05, to detect lack of benefit of CIAR on the outcome of IAS; that is, adverse effects of poor runoff on iliac stent patency could not be improved with CIAR.

In a previous study[18] we demonstrated that poor infrainguinal runoff is the main risk factor for decreased primary patency after both IAS and aortoiliac surgical reconstruction in patients with moderately severe iliac occlusive disease, that is, TASC type B and C iliac lesions. Although inadequate runoff affects all types of inflow procedures, outcome was significantly better in patients undergoing aortoiliac surgical reconstruction compared with those undergoing iliac artery angioplasty and stenting. Because CIAR does not improve outcome of IAS in patients with poor runoff, aortoiliac surgical reconstruction still offers the best long-term results in this subgroup of patients.

There are several potential limitations to our study. First, ours is a retrospective observational study, with the potential bias and confounding effects inherent in all observational studies. Second, although we included patients from two busy institutions with ample experience in both endovascular and peripheral reconstruction, the number of patients was small and prevented further stratified analysis free from type II statistical error. Although only a randomized clinical trial could assess the exact influence of concomitant infrainguinal arterial reconstruction in patients undergoing iliac artery angioplasty and stenting to treat iliac occlusive disease with inadequate infrainguinal runoff, such trial has not been performed and is unlikely to be conducted in the future. Consequently, we must rely on data from observational studies to draw conclusions and make recommendations. The information obtained in this study may therefore be useful to vascular surgeons, to determine need for iliac artery angioplasty and stenting with concomitant infrainguinal arterial reconstruction. Inasmuch as many vascular surgeons have adopted the strategy of concomitant procedures, considering this approach more cost-effective and convenient for patients, the present study indicates that concomitant infrainguinal arterial reconstruction is not always justified.

Although other methods of improving infrainguinal outflow in patients with poor runoff, such as superior femoral artery angioplasty or stenting and subintimal angioplasty of crural vessels, were not assessed in this study, these procedures would probably not offer additional benefit in terms of primary iliac stent patency, compared with CIAR. However, these procedures are an attractive alternative to CIAR, because they are less invasive and outcome seems to be improving with experience.[19,20]

In conclusion, our data suggest that CIAR does not improve iliac stent patency in patients undergoing IAS in whom iliac lesions are associated with poor distal runoff. Infrainguinal bypass procedures should therefore be reserved for patients in whom clinical improvement is not noted after IAS and possibly for those with limb-threatening ischemia.

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DISCUSSION

Dr Eugene M. Langan III, MD (Greenville, SC). The group from the University of Tennessee–Knoxville, now in concert with the Montefiore group again, present their data on iliac artery angioplasty and/or stenting. As this is the third consecutive year a variant of this data is presented at this meeting, they have won a virtual trifecta on iliac artery stenting.

This year they added to last year's report and become more specific to assess the effects of concomitant infrainguinal reconstruction on iliac stent patency. Of the 394 iliac artery stent procedures performed over a 52-year experience, 68, or 17%, in 62 patients were associated with poor distal runoff. Distal revascularization was done in 31 patients, 25 or 81%, at the same operative setting. Concerning to me is that 12 patients, or 44% of the combined group, underwent concomitant lower extremity vascularization and iliac stenting for claudication. I would suggest that this is possibly overaggressive therapy and that these patients may have significant improvement in ambulatory status without the added, more invasive therapy. This also could be part of the reason that Dr Timaran and his colleagues have found that distal revascularization at the same setting as iliac artery stenting may not always be justified.

This paper also brings out a trend that is not highlighted but is extremely important. There was a trend for improved limb salvage with the combined procedures. This makes intuitive sense. In our program, lower extremity revascularization is not performed to assist in iliac artery endovascular intervention, but to improve distal lower extremity perfusion. This seems to fit the authors' conclusion.

A point of interest and evolution in this group's work is that in this study all procedures were performed by vascular surgeons. In the original paper only 2 years ago, interventional radiologists did the majority of the iliac interventions. This is a change I applaud.

I have a few questions for Dr Timaran. Carlos, you state in the manuscript that all revisions or occlusions were considered a stent failure. I am unclear if this is a bypass graft revision or a more proximal stent revision. If it is the bypass graft, should this affect stent patency? Could you please comment on this?

Next, in your previous studies renal failure was a marker for iliac stenting failure. It makes sense that this would hold true for patients requiring distal bypass. What is your opinion on the change?

Last, we feel that there is great value to the profunda femoral runoff, and at times will add profundaplasty to assist our distal perfusion. Did your study point to any value of profundaplasty?

Dr Carlos H. Timaran. Regarding your first question, we did try to separate primary iliac stent patency from the graft patency of the infrainguinal arterial reconstructions. In most cases, this was possible. We also used an extended Cox regression model that allowed us to include time-depen-